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[Continued on next page]

(54) Title: DRUG AUTHENTICATION

Table 1. Level 1 Component and Composition Changes for Immediate Release Oral Solid Dosage Forms

Excipient	Percent Excipient (w/w) Out of Total Target Dosage Form Weight
Filler	+/- 5%
Disintegrant	+/- 3%
starch	+/- 1%
other	+/- 0.5%
Binder	+/- 0.25%
Lubricant	+/- 1%
calcium or magnesium stearate	+/- 1%
other	+/- 0.1%
Glidant	+/- 1%
talc	+/- 0.1%
other	+/- 1%
Film coat	+/- 1%

Table 2. Level 2 Component and Composition Changes for Immediate Release Oral Solid Dosage Forms

Excipient	Percent Excipient (w/w) Out of Total Target Dosage Form Weight
Filler	+/- 10%
Disintegrant	+/- 6%
starch	+/- 2%
other	+/- 1%
Binder	+/- 0.5%
Lubricant	+/- 2%
calcium or magnesium stearate	+/- 2%
other	+/- 0.2%
Glidant	+/- 2%
talc	+/- 0.2%
other	+/- 2%

WO 2005/031302 A2

(57) Abstract: A method is disclosed to verify and identify pharmaceutical products through their product signatures in order to combat counterfeiting and reduce dispensing errors, using methods such as near infrared spectroscopy. Furthermore, in order actively evade pharmaceutical product counterfeiting, a method is disclosed where an amount of one or more of the inactive ingredients is varied over time; the variation provides a different product signature, but falling within a level deemed permissible by a regulatory body.



FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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